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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/331,631 | 06/21/1999 | JOHN MICHAEL MANNERS | CULLN23.001A | 1902 |

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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 07/16/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/331,631

Applicant(s)
Manners et al.

Examiner
Hope Robinson

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1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 17, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 11-21, 30, 31, 33, 34, 36, 37, and 39-45 is/are pending in the application.
- 4a) Of the above, claim(s) 12, 14, 15, 33, 34, 36, 37, and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11, 13, 16-21, 30, 31, and 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. The request filed on April 4, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/331,631 is acceptable and a CPA has been established. An action on the CPA follows. The finality of the previous office action has been withdrawn. It is noted that applicant filed a Declaration under 37 CFR 1.132 and corrected drawings which have been entered.

2. Applicant's response to the Office Action mailed December 4, 2001 in Paper No. 14 on April 4, 2002 is acknowledged.

3. Claims 22 and 23 have been canceled. Claims 43-45 have been added. Claims 1, 2, 16, 17, 18, 19, 20, 21, 30, 31, 34, 39 and 42 have been amended. Claims 1-3, 11-21, 30, 31, 34, 36, 37, 39-45 are pending. Claim 31 as amended has been rejoined. Claims 1-3, 11, 13, 16-21, 30, 31 and 41-45 are under examination.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter (See 37 CFR 1.75(d)(1) and MPEP § 608.01(o)). Correction of the following is required: the added material which is not supported by the original disclosure is as follows: claim 1 has been amended to read that "X is any amino acid residue other than cysteine".

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The specification provides no support for this amendment see for example pages 4 and 10 where it is disclosed that "X is any amino acid residue".

Specification

5. The specification is objected to because of the following informalities:

The specification is objected to because on page 26 the word "agains" appears instead of "against". Correction is required.

6. The amendment filed September 17, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claim 1 has been amended to read that "X is any amino acid residue other than cysteine". The specification provides no support for this amendment see for example pages 4 and 10 where it is disclosed that "X is any amino acid residue".

Applicant is required to cancel the new matter in the reply to this Office action.

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Claim Rejections - 35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 13 and 43-45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Note that claims 43-45 are directed to methods with no method steps *per se*. As the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. For example claim 43 recites “a method of controlling microbial infestation of a plant, the method comprising treating said plant”. The claim does not have any recitation of how to treat which is the positive method step that is missing, for example “a method of controlling microbial infestation in a plant, said method comprising administering an effective amount of the composition...” (see also claim 45). Note that claim 44 recites “reducing the number of fungi”, however, this can be construed as a result not a method step as the method does not set forth how to reduce the number of fungi (see also claim 13). Without setting forth any steps involved in the process/method, results in an improper definition of a process and is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3, 11, 13, 16-21, 30, 31 and 41-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is directed to a purified or isolated protein fragment having antimicrobial activity and methods of controlling microbial infestation. Claim 1 and the dependent claims hereto introduced new matter into the claims because it is recited that "X is any amino acid residue other than cysteine". The specification provides no support for this amendment see for example pages 4 and 10 where it is disclosed that "X is any amino acid residue". In addition, the claimed invention has not been adequately described as claim 16 requires the use of a "known" sequence in the claimed method and there is no indicia as to what sequence, to whom the sequence is known or how to identify this sequence. Does any sequence apply to applicant's method? Furthermore, the claims are directed to methods of controlling microbial infestation and the methods do not provide any method steps to enable one skilled in the art to practice the claimed invention. The claims broadly recite that the protein has antimicrobial activity, however, note that example 15 (Table 1) lists 15

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organisms and only 5 organism exhibited 50% inhibition of growth with the composition used (see page 29 of the specification). This demonstrates antimicrobial activity to some extent, however, does not provide sufficient guidance as to a method to control microbial infestation. Note also that the specification on page 29 supports this conclusion by stating that there was a reduction observed but not an elimination. Thus, it is apparent that the specification lacks sufficient guidance/written description for one of skill in the art to be able to practice the claimed invention without performing undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3, 11, 13, 16-18, 20-21 and 41-45 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 11, 13 and 17-21 lack antecedent basis for the phrase "X is any amino acid other than cysteine" as the specification does not provide support for this phrase.

Claim 3 is indefinite because the claim does not recite the proper markush language "selected from the group consisting of".

Claim 13 is indefinite because the claim is a method claim which improperly depends from a product claim. The claim is further indefinite as the method does not recite any positive method steps to achieve the objective of the method. In addition, the claim recites a "method of

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controlling microbial infestation” and the end result is “reduction of microbes” which is inconsistent with the preamble of the claim.

Claim 16 is indefinite because of the recitation of “identifying in a known sequence or designing an amino acid sequence” as the claimed method does not provide any steps as to how to “identify in a known sequence”. The claim is further indefinite with regard to “identifying in a known sequence”, to whom is the sequence known? The claim is also indefinite as it is not apparent which residues would or would not be substituted and in what positions. The dependent claims are also included in this rejection.

Claim 43 is indefinite because the preamble of the claim recites a method of controlling microbial infestation of a plant and the end result is to inhibit microbial infestation of the plant. Note that there’s no consistency in the action taken in the method. Note also that the claim also recites “infestation of a plant” rather than “ infestation in a plant” (see also claims 44-45).

Claims 43-45 are indefinite because the claims directed to methods without any positive method step, thus it is unclear how to effectively achieve the objective of the method.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claim 1 remains rejected under 35 U.S.C. 102 (a) as being anticipated by Tatar et al. (EP 093652, November 9, 1996).

Tatar disclose peptides used to vaccinate against *E. coli* enterotoxins. In addition, Tatar disclose the sequence contained in SEQ ID No: 39 with the formula C3XC12XC3XC wherein X is any amino acid and C is cysteine, with a 100% sequence identity. Therefore, the limitation of the claim is met by this reference (see sequence alignment and pages 1-2 of the reference).

11. Claim 1 remains rejected under 35 U.S.C. 102 (a) as being anticipated by Voerman (WO 96/13585, May 9, 1996).

Voerman disclose protease inhibitors obtainable from leeches. Voerman also disclose a medicament and pharmaceutical preparations. Voerman further disclose the sequence contained in SEQ ID No: 37 with a 100% sequence identity where the sequence is C3XC10XC3XC, wherein X is any amino acid and C is cysteine (see the alignment and abstract). Therefore, the limitation of the claim is met by this reference (see sequence alignment and pages 1-2 of the reference).

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12. Applicant's arguments filed on April 4, 2002 in Paper No. 14 have been fully considered but were not persuasive. Note that the rejections under 35 U.S.C. 112, first and second paragraph and 102(a) remains. In addition, new grounds of rejections have been added for the reasons stated above. Regarding the rejection under 35 U.S.C. 112, first paragraph with respect to the issue of new matter presented in the amendment filed September 17, 2001, applicant contends that support for the terminology can be found on page 10 lines 6 to 16 and quotes a paragraph on page 6 of the response. However, this contention is not accurate as the paragraph does not specifically state that "X is any amino acid other than cysteine". Applicant states that from the cited paragraph applicants intended cysteine to be excluded from the definition of X given in line 15, however, what was intended by applicant and what is disclosed differs.

Applicant's intention cannot be read into the claims or the disclosure, what is disclosed or recited is what is considered during examination. Further, the cited paragraph appears to argue for the presence of cysteine not the exclusion of it as "X". Thus, this argument is not persuasive and the rejection remains. Hence the maintenance of the rejections under 35 U.S.C. 102(a) as the references remain applicable since applicant did not cancel the new matter material (as addressed on pages 10-11 of the response). The Declaration submitted under 37 CFR 1.132 has been considered. However, not persuasive because the recitation of the negative limitation inserted into the claim by the amendment is new matter as the phrase "X is any amino acid other than cysteine" is not supported by the instant specification. Therefore, the claim can be interpreted in the way that the art has been applied.

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With regard to the rejection under 35 U.S.C. 112, second paragraph, note that new grounds of rejection has been instituted for the stated reasons above. The rejections of record remain because applicant's arguments were not persuasive. In particular page 8 of the response states that claim 16 does not need to have a step that indicates how to identify a sequence which forms a helix-turn-helix, however, the claim recites in step (a) "identifying in a known sequence or designing an amino acid sequence", it is unclear whom the sequence is known, which sequence to use and how to identify this known sequence. Thus the rejection remains.

Conclusion

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's

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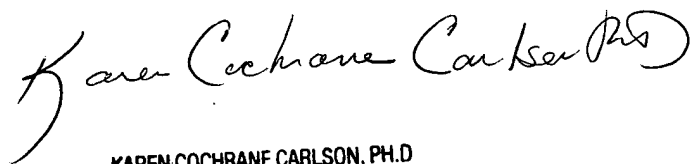
name on a cover sheet attached to your communication should you choose to fax your response.

The faxing of such papers must conform with the notice published in the Official Gazette, 1096

OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER